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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/654,323	09/01/2000	Michael R. Hayden	50110/004002	5878

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EXAMINER
STEADMAN, DAVID J

ART UNIT	PAPER NUMBER
1652	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/654,323	HAYDEN ET AL.	
	Examiner	Art Unit	
	David J. Steadman	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-79 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-79 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Application Status

Claims 1-79 are pending in the application.

Receipt of a computer readable form of the sequence listing and a paper copy thereof in Paper No. 01/16/02 is acknowledged.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claim(s) 1-4, drawn to a method for treating a patient diagnosed as having a lower than normal HDL-cholesterol level, a higher than normal triglyceride level, or a cardiovascular disease by administering a compound that modulates liver X receptor (LXR)-mediated transcriptional activity, classified in class 514, subclass 789.

II. Claim(s) 5 and 6, drawn to a method for treating a patient diagnosed as having a lower than normal HDL-cholesterol level, a higher than normal triglyceride level, or a cardiovascular disease by administering a compound that modulates retinoid X receptor (RXR)-mediated transcriptional activity, classified in class 514, subclass 789.

III. Claim(s) 7-9, drawn to a method for determining whether a candidate compound modulates ABC1 expression, classified in class 435, subclass 6.

IV. Claim(s) 10, 11, 13, and 14, drawn to a nucleic acid comprising a region that is identical to nucleotides 1-28,707 of SEQ ID NO:1, classified in class 536, subclass 23.1.

V. Claim(s) 10 and 12-14, drawn to a nucleic acid comprising a region that is identical to nucleotides 29,011-53,228 of SEQ ID NO:1, classified in class 536, subclass 23.1.

VI. Claim(s) 15-19, drawn to a method for treating a human having a higher than normal triglyceride level by administering the ABC1 polypeptide or triglyceride-regulating fragment thereof of SEQ ID NO:5 (wild-type ABC1), SEQ ID NO:5 with an R219K mutation (R219K ABC1), SEQ ID NO:5 with a V399A mutation (V399A ABC1), and ABC1

polypeptides with a mutation that increases protein stability or biological activity, classified in class 514, subclass 2.

VII. Claim(s) 20-26, drawn to a method for treating a human having a higher than normal triglyceride level by administering a polynucleotide encoding the ABC1 polypeptide or triglyceride-regulating fragment thereof of SEQ ID NO:5, R219K ABC1, V399A ABC1, and ABC1 polypeptides with a mutation that increases protein stability or biological activity, classified in class 514, subclass 44.

VIII. Claim(s) 27, drawn to a method for treating a human having a higher than normal triglyceride level by administering a compound that increases ABC1 biological activity or mimics the activity of wild-type ABC1, R219K ABC1, or V399A ABC1, classified in class 514, subclass 789.

IX. Claim(s) 28, drawn to a non-human mammal comprising a transgene comprising a polynucleotide encoding an ABC1 polyeptide with a M1091T mutation (M1091T ABC1), classified in class 800, subclass 13.

X. Claim(s) 29, drawn to a method for determining whether a compound decreases the inhibition of M1091T ABC1 using a cell expressing a dominant-negative ABC1 polypeptide, classified in class 435, subclass 19.

XI. Claim(s) 30, drawn to a method for predicting a person's response to a triglyceride-lowering drug by determining whether the person has a polymorphism in an ABC1 gene, promoter, or regulatory sequence, classified in class 435, subclass 6.

XII. Claim(s) 31, 32, and 46-49, drawn to a method for determining whether a candidate compound is useful for modulating triglyceride levels by providing a candidate compound to a chicken comprising a mutation in an ABC1 gene and measuring ABC1 biological activity, classified in class 435, subclass 19.

XIII. Claim(s) 33-37, 39, and 41-49, drawn to a method for determining whether a candidate compound is useful for modulating triglyceride levels by contacting an ABC1 polypeptide

comprising amino acids 1-60 of SEQ ID NO:5 or a cell expressing an ABC1 polypeptide comprising amino acids 1-60 of SEQ ID NO:5 or ABC1 gene or fragment thereof with a candidate compound and measuring ABC1 biological activity, half-life, expression, or binding, classified in class 435, subclass 19.

XIV. Claim(s) 38 and 41-45, drawn to a method for determining whether a candidate compound is useful for modulating triglyceride levels by contacting an ABC1 polypeptide comprising amino acids 1-60 of SEQ ID NO:5 with a second polypeptide that interacts with said ABC1 polypeptide and a candidate compound and measuring ABC1 polypeptide interaction with said second polypeptide, classified in class 435, subclass 19.

XV. Claim(s) 40 and 41-45, drawn to a method for determining whether a candidate compound is useful for modulating triglyceride levels by contacting an ABC1 polypeptide in a lipid membrane with a candidate compound and measuring ABC-1 mediated lipid transport, classified in class 435, subclass 19.

XVI. Claim(s) 50-53, drawn to a method of determining a propensity for a lower than normal HDL level, a higher than normal triglyceride level, and a cardiovascular disease by determining the presence or absence of at least one ABC1 polymorphism in an ABC1 polynucleotide or polypetpide sequence, classified in class 435, subclass 6.

XVII. Claim(s) 54, drawn to an electronic database comprising sequence records of ABC1 polymorphisms, classified in class 707, subclass 1.

XVIII. Claim(s) 55 and 56, drawn to a method for selecting a preferred therapy for modulating ABC1 activity or expression by determining the presence or absence of at least one ABC1 polymorphism in an ABC1 polynucleotide or polypetpide sequence, classified in class 435, subclass 6.

XIX. Claim(s) 57-62, drawn to a method for determining whether a candidate compound is useful for treatment of or a method for identifying a compound to be tested for an ability to treat a lower than normal HDL level, a higher than normal triglyceride level, and a

cardiovascular disease by measuring ABC1 biological activity, classified in class 435, subclass 19.

XX. Claim(s) 57-61 and 63, drawn to a method for determining whether a candidate compound is useful for treatment of or a method for identifying a compound to be tested for an ability to treat a lower than normal HDL level, a higher than normal triglyceride level, and a cardiovascular disease by measuring ABC1 phosphorlyation, classified in class 514, subclass 789.

XXI. Claim(s) 60, drawn to a method for identifying a compound to be tested for an ability to treat a lower than normal HDL level, a higher than normal triglyceride level, and a cardiovascular disease by measuring ABC1 expression, classified in class 435, subclass 6.

XXII. Claim(s) 64-69, drawn to a compound that modulates ABC1 biological activity for treatment of a lower than normal HDL level, a higher than normal triglyceride level, and a cardiovascular disease, classified in class 514, subclass 789.

XXIII. Claim(s) 70 and 74, drawn to a method for determining whether a candidate compound is useful for treatment of a lower than normal HDL level, a higher than normal triglyceride level, and a cardiovascular disease by contacting an assay system with a compound and measuring LXR biological activity, classified in class 435, subclass 7.1.

XXIV. Claim(s) 71-74, 76, and 79, drawn to a method for determining whether a candidate compound is useful for modulating ABC1 biological activity by contacting an assay system with a compound and measuring LXR biological activity, classified in class 435, subclass 19.

XXV. Claim(s) 75 and 79, drawn to a use of a compound that modulates activity or expression of LXR for the treatment of a lower than normal HDL level, a higher than normal triglyceride level, and a cardiovascular disease, classified in class 514, subclass 789.

XXVI. Claim(s) 77 and 79, drawn to a method for screening a candidate LXR agonist for the ability to treat a lower than normal HDL level, a higher than normal triglyceride level, and

a cardiovascular disease by contacting a cell with a candidate LXR agonist and measuring cholesterol efflux activity of the cell, classified in class 435, subclass 19.

XXVII. Claim(s) 78 and 79, drawn to a method for screening a candidate LXR modulating compound for the ability to treat a lower than normal HDL level, a higher than normal triglyceride level, and a cardiovascular disease by contacting a cell with a candidate LXR modulating compound and measuring ABC1 biological activity of the cell, classified in class 435, subclass 19.

2. The inventions are distinct, each from the other because:

3. The methods of Groups I-III, VI-VIII, X-XVI, XVIII-XXI, and XXIII-XXVII are independent as they comprise different steps, utilize different products and yield different results.

4. The nucleic acids of Groups IV and V are structurally distinct and encode different polypeptides. Therefore, where structural identity is required, such as for polypeptide expression, the Groups have different effects.

5. The nucleic acids of Groups IV and V, the transgenic non-human mammal of Group IX, the electronic database of Group XVII, and the compound of Group XXII each comprises a chemically unrelated structure capable of separate manufacture, use, and effect. The nucleic acids of Groups IV and V have other utility besides encoding polypeptides such as hybridization probes, the transgenic non-human mammal of Group IX can be used to identify a compound that decreases inhibition of M1091T ABC1, the electronic database of Group XVII can be used to electronically store a record of ABC1 polymorphisms, and the compound of XXII can be used to modulate ABC1 biological activity.

6. The nucleic acids of Groups IV and V are unrelated to the method(s) of Groups I-III, VI-VIII, X-XVI, XVIII-XXI, and XXIII-XXVII as they are neither used nor made by the method(s) of Groups I-III, VI-VIII, X-XVI, XVIII-XXI, and XXIII-XXVII.

7. The transgenic non-human mammal of Group IX is unrelated to the method(s) of Groups I-III, VI-VIII, X-XVI, XVIII-XXI, and XXIII-XXVII as they are neither used nor made by the method(s) of Groups I-III, VI-VIII, X-XVI, XVIII-XXI, and XXIII-XXVII.

8. The electronic database of Group XVII is unrelated to the method(s) of Groups I-III, VI-VIII, X-XVI, XVIII-XXI, and XXIII-XXVII as they are neither used nor made by the method(s) of Groups I-III, VI-VIII, X-XVI, XVIII-XXI, and XXIII-XXVII.

9. The compound of Group XXII is unrelated to the method(s) of Groups I-III, VI, VII, X, XI, XIV-XVI, XVIII, XX, XXI, and XXIII-XXVII as they are neither used nor made by the method(s) of Groups I-III, VI, VII, X, XI, XIV-XVI, XVIII, XX, XXI, and XXIII-XXVII.

10. The compound of Group XXII and the methods of Groups VIII, XII, XIII, and XIX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the compound of Group XXII can be used as an affinity purification reagent for the purification of an ABC1 polypeptide.

11. The methods of Groups I-III, VI-VIII, X-XVI, XVIII-XXI, and XXIII-XXVII are independent as they comprise different steps, utilize different products and yield different results.

12. Because these inventions are distinct for the reasons given above, have separate classifications, and/or each of the inventions listed as Groups I-XXVII requires a separate search, restriction for examination purposes as indicated is proper. "For purposes of the initial requirement, a serious burden on the examiner may be *prima facie* shown if the examiner shows by appropriate explanation either separate classification, separate status in the art, or a different field of search as defined in MPEP 808.02" (see MPEP 803). The inventions listed as Groups I-XXVII require divergent patent and non-patent literature and sequence searches, thus establishing the serious burden of search on the examiner.

13. Claim 3 is generic to a plurality of disclosed patentably distinct species comprising the compounds as set forth in the claim. Each of these compounds comprises a different structure. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

14. It is noted that claims 10, 41-49, 57-59, 74, and 79 will be examined to the extent the claims read on the elected subject matter.

Conclusion

15. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

16. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Steadman, whose telephone number is (703) 308-3934. The Examiner can normally be reached Monday-Friday from 7:30 am to 2:00 pm and from 3:30 pm to 5:30 pm. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (703) 308-3804. The FAX number for this Group is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Art Unit receptionist whose telephone number is (703) 308-0196.

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